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STUDY OF THE REACTION TO CHEMICALLY SORBED ANTHRAX VACCINE IN SMALL GROUPS OF PEOPLE

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STUDY OF THE REACTION TO CHEMICALLY SORBED ANTHRAX VACCINE IN SMALL GROUPS OF PEOPLE

[Following is the translation of an article by N. I. Aleksandrov, N. Ye. Gefen, A. P. Budak, V. F. Runova, Yu. V. Yezepchuk and A. G. Bachinov, published in the Russian-language periodical Zhurnal Mikrobiologii, Epidemiologii i Immunobiologii (Journal of Microbiology, Epidemiology and Immunobiology), No. 3, 1963, pages 32-34. It was submitted on 25 Feb 1961. Translation performed by Sp/7 Charles T. Ostertag Jr.]

The high immunogenic effectiveness and harmlessness of chemically sorbed anthrax vaccine, established in experiments on animals (Aleksandrov et al., 1961 and 1963; Bazhinov and Kamorskiy, 1960), made it possible to switch to the study of its reaction in small groups of people.

The study of the reaction to chemically sorbed anthrax vaccine was carried out with two doses -- 10 mg with two administrations of 5 mg each with an interval of 17 days (first group) and 7.5 mg with two administrations (2.5 mg in the first and 5 mg in the second) with a 7 day interval (second group). After the preliminary verification of its sterility the vaccine was administered subcutaneously in the subscapular region of the spine.

Sterilization of the vaccine was done by means of treating it with beta-propiolactone (0.5%) which possesses an exceptionally high bactericidal activity. Following treatment with beta-propiolactone the vaccine maintained its immunogenic activity and harmlessness for the organism, which was established by us in specially conducted investigations.

The reaction to chemically sorbed anthrax vaccine was evaluated, based on the indices of the general and local reaction to the inoculation.

From the data presented in table 1 it is seen that out of 8 persons vaccinated in the first group, in 24 hours following the initial administration of 5 mg of chemical vaccine, in 5 persons a weak (37.1--37.5°) general reaction (temperature change) to the inoculation was noted and in 2 -- an average intensity (37.6--38.5°). In the second 24 hours a weak general reaction was manifested in only half of those inoculated. On the third day the general reaction was lacking and the temperature in all those vaccinated was normal. All of those vaccinated felt completely healthy and able to work.

Upon clinical investigation of the blood at 24 hours following the inoculation, in the first group an increase of  $1\frac{1}{2}$  -- 2 times was detected in the number of leukocytes, a small speeding up of the ESR [ESR = erythrocyte sedimentation rate] and a change in the leukocytic formula due to a certain increase in the amount of segmentonuclear neutrophils. On the tenth day following inoculation all the indices were back to normal.

The local reaction to inoculation was insignificant. In all 8 persons inoculated, an edematous condition was noted at the site of injection for 2-3 days with minor painfulness and reddening. Swelling and painfulness of the regional lymph nodes were not noted in one of those inoculated.

On the 17th day following a single administration of 5 mg of vaccine, a test with anthraxin was positive (sharply expressed) in 4 out of 8 inoculated.

The repeated administration of 5 mg of chemically sorbed anthrax vaccine caused symptoms analogous to those observed during its initial administration.

On the 14th day following the repeated introduction of the vaccine, a sharply expressed cutaneous allergic reaction to the intracutaneous administration of anthraxin was observed in 7 out of the 8 who were vaccinated. This testified to the immunological alteration of the organism of those inoculated.

In the second group, which was inoculated with 2.5 mg of vaccine, the reaction, especially the general one, was considerably weaker. A general reaction of average intensity with an increase of temperature up to  $37.8^{\circ}$  was observed in only one out of 4 persons. On the second day a banal inflammation of the upper respiratory tract was established in the one person. In 24 hours following the first administration of vaccine, the same changes on the part of the blood were noted in these people as in those vaccinated in the first group.

The repeated administration of 5 mg of chemical vaccine did not cause a general reaction. Changes in the blood picture (acceleration of the ESR, leukocytosis and an increase of segmentonuclear neutrophil count) and the local reactions to the administration of the vaccine (edematous condition and minor painfulness rapidly coming to an end by the 2nd--3rd day) in them were analogous to those described above for members of the first group.

On the seventh day following the repeated administration of the chemical vaccine a sharply expressed cutaneous reaction to the intracutaneous administration of anthraxin was observed in all those inoculated.

Changes observed in the blood of persons of both groups after the first and second administration of chemical vaccine testified to the presence of a specific, sufficiently expressed, immunization stimulation, caused by the vaccine preparation. The clearly expressed positive intracutaneous allergic test with anthraxin testified to a known degree concerning the specific immune alteration of the organism in response to the introduction of chemically sorbed anthrax vaccine.

#### Conclusions

1. Chemically sorbed anthrax vaccine, following two subcutaneous administrations in doses of 2.5 and 5 mg, or 5 and 5 mg, turned out to be harmless and moderately reactogenic. The general and local reactions observed in those inoculated were regarded as mild and did not cause any loss of the ability to work.
2. Changes of the blood picture (leukocytosis, ESR and leukocytic formula), observed in those inoculated in a period from the 1st through the 10th day following the first and second administration of chemical vaccine, testified to the specific, sufficiently expressed, immunization stimulation of the lymphatic system.
3. The clearly expressed positive allergic test with anthraxin (anthrax allergen), observed in 11 out of 12, testified to the specific immune alteration, caused by the introduction of chemically sorbed anthrax vaccine.
4. The results of the study of the reactogenicity of chemically sorbed anthrax vaccine in small groups of people give a foundation to make a conclusion concerning the suitability of this vaccine preparation for the immunization of people and opens up the possibility for the subsequent wider study of the preparation (determining its optimum immunizing dose, rational methods of immunization, immunological, epidemiological and epizootiological effectiveness).

#### Literature

- a. Aleksandrov, N. I., Gefan, N. Ye., Budak, A. P., et al., J. of Microbiology, 1961, No. 5, p. 42.
- b. Bazhinov, A. G., Kamorskiy, N. M., Ibid, 1960, No. 7, p. 26.

[Following is the English summary which appears with the Russian article.]

Repository chemical sorbed anthrax vaccine given in doses of 10 and 7.5 mg proved to harmless and gave only mild postvaccinal reactions when injected subcutaneously to human beings. General and local reactions observed in the immunized individuals were mild and did not cause any loss of the working capacity. Changes in the blood picture (leukocytosis, accelerated erythrocyte sedimentation rate and rise of the segmentonuclear neutrophil count) and a marked positive test with anthraxin (anthrax allergen) noted almost in all the vaccinated individuals testifies to the presence of a specific, sufficiently marked immunization stimulation caused by the administration of repository chemical sorbed anthrax vaccine.

General and local reaction in persons inoculated with chemical anthrax sorbed vaccine

Group of persons inoculated	Inoculation	Number inoculated	General Reaction						Local Reaction		
			Number of persons with reactions of a various degree in various periods (in hours)						Edematous condition	Painfulness	Enlargement of regional lymph nodes
			24		48		72				
			Weak age	Average	Weak age	Average	Weak age	Average			
			First	1st	8	6	2	4			
	2nd	8	4	4	2	0	0	0	4	0	
Second	1st	4	3	1	0	1	0	1	4	0	
	2nd	4	0	0	0	0	0	0	4	0	